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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,716	05/02/2001	Soren Nielsen	NIELSEN=3A	3819

1444 7590 07/01/2005  
BROWDY AND NEIMARK, P.L.L.C.  
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WASHINGTON, DC 20001-5303

EXAMINER

DEBERRY, REGINA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/845,716

Applicant(s)

NIELSEN ET AL.

Examiner

Regina M. DeBerry

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,5 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4,5 and 12-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

***Status of Application, Amendments and/or Claims***

The amendment filed 21 May 2005 has been entered in full. Claims 1, 2, 4, 5, and 13-17 are pending. Claim 11 is under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**Objections**

Applicant has submitted the Declaration of Thomas Jonassen (12 May 2005). The instant declaration, while considered, is objected to because it is not clear whether the declaration has been submitted under 37 CFR 1.131 or 37 CFR 1.132.

**Claim Rejections - 35 USC 103**

The Declaration of Thomas Jonassen filed 12 May 2005 is insufficient to overcome the rejection of claim 11 based upon 35 U.S.C. 103(a) as being unpatentable over Shohaib *et al.*, (Nephron 1999281:81-83) in view of Kwon *et al.*, (American Journal of Physiology 1999 Sept 277, 3 Pt 2, F413-27).

Claim 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Shohaib *et al.*, (Nephron 1999281:81-83) in view of Kwon *et al.*, (American Journal of Physiology 1999 Sept 277, 3 Pt 2, F413-27). The basis for this rejection is set forth at pages 3-4 of the previous Office Action (14 January 2005).

Applicant argues that the two references do not describe the use of EPO and alpha-MSH, respectively, for the same purpose. Applicant states that in support of their position, the enclosed declaration of Dr. Thomas Jonassen has been submitted.

Dr. Jonassen states that Shohaib et al. do not describe the treatment of renal failure, but instead describe the use of EPO in the treatment of anaemia in post-treatment transplant patients. Dr. Jonassen states that Kwon et al. teach that alpha-MSH treatments of rats with acute renal failure results in a reduced ischemia-induced downregulation of renal aquaporins and in a reduced polyuria. Dr. Jonassen states that this is not the same as teaching the use of alpha-MSH for the treatment of anaemia. Dr. Jonassen contends that anaemia is not observed in acute renal failure. Applicant concludes that Shohaib et al. and Kwon et al. do not teach the use of EPO and alpha-MSH, respectively, for the same purpose and thus, it is not obvious to combine EPO and alpha-MSH in a composition.

Applicant's arguments have been fully considered but are not deemed persuasive. Shohaib et al. teach the use of EPO in post-renal transplant patients. Shohaib et al. state, "EPO has been reported to be effective in treating anaemia due to chronic renal failure". "It has been used in pregnancy to correct anemia following renal transplantation with graft dysfunction" (abstract). Kwon et al. teach that alpha-MSH treatments of rats with acute renal failure result in a reduced ischemia-induced downregulation of renal aquaporins and in a reduced polyuria. Kwon et al. states that trials to modulate the expression of water channel proteins and sodium transporters may potentially provide relevant therapeutic modalities in ischemia-induced acute renal failure of human patients. The references demonstrate the use of EPO and alpha-MSH in the same patient population (renal failure patients). Anaemia, kidney ischemia and polyuria can all occur in renal failure. Thus, it would be obvious to combine the two

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compositions for the same purpose, treating renal failure patients. Lastly, contrary to Applicant's assertion, anaemia has been observed in acute renal failure patients. The Examiner has provided references to demonstrate this.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

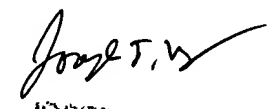
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RMD  
6/25/05

  
JOSEPH MURPHY  
PATENT EXAMINER